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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/12/2001

Jean-Marc Balloul

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05/19/2006

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,899

Applicant(s)

BALLOUL ET AL.

Examiner

Agnieszka Boesen

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-7 and 10-25 is/are pending in the application.
- 4a) Of the above claim(s) 7, 16, 17 and 19-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 10-15, 18, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants's Amendment filed April 24, 2006 in response to the Office Action on January 24, 2006 is acknowledged and has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Examiner Agnieszka Boesen Group Art Unit 1648**.

Upon further consideration the finality of the previous Office Action of January 24, 2006 is withdrawn. Prosecution is reopened to make the following rejections. Any inconvenience is regretted.

Specification

The specification is objected to for containing an embedded hyperlink, which is impermissible and requires deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is

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considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference. Appropriate correction is required.

Claim Objections

The objection of claim 3, 6, 13-15, and 24 for depending from a rejected base claim is **withdrawn** in view of the new ground of rejection set forth in this office action.

Claim Rejections - 35 USC § 112

The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicant regards as the invention, **is withdrawn** in view of Applicant's amendment to the claims.

The rejection of claim 5 is maintained and claims 1-3, 6, 10-15, 18, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with enablement requirement.

Upon further consideration, claims 1-3, 6, 10-15, 18, 24, and 25 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with enablement requirement.

The amended claim 5 and claims 1-3, 6, 10-15, 18, 24, and 25 are drawn to the poxviral particle, wherein the ligand moiety localized at the surface of the poxviral particle binds to tumor-specific antigen or a cellular protein selected from the group consisting of the receptor for

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interleukin 2 (IL-2), GRP (Gastrin Release Peptide), TNF (Tumor Necrosis Factor), epidermal growth factor receptors, Fas receptor, CD40 receptor, CD30 receptor, CD27 receptor, OX-40, Alpha v integrins, receptors for angiogenic growth factors, and a gene product of a cancer associated virus. A poxviral particle has a targeted infection specificity, which is conferred by the binding of at least one ligand moiety localized on the surface of the poxviral particle to an anti-ligand molecule localized at the surface of the target cells.

Cellular proteins such as receptors for interleukin 2 (IL-2), TNF (Tumor Necrosis Factor), epidermal growth factor receptors, Fas receptor, CD40 receptor, CD30 receptor, CD27 receptor, OX-40, Alpha v integrins are expressed on not only tumor cells but also on non-tumor, normal, non-pathologically altered cells (see Janeway *et al.* Immunobiology, Fourth Edition, page 187, 278, and 291). Thus, when the claimed ligand moiety localized at the surface of the poxviral particle will bind to one of the cellular proteins listed above, the normal, non-tumor cell will be infected. The current specification does not describe how the viral particle with specificity for the particular receptor (protein), will spare infecting normal cells. The infection and elimination of normal cells would not be desired. Even though the specification describes that the poxviral particle will recognize cellular proteins that are overexpressed (page 10), there is lack of guidance as to how to avoid the viral particles from infecting normal cells.

Regardless of the degree of expression of the cellular proteins (overexpressed, underexpressed or normal expression), the ligand moiety is not expected to distinguish between levels of expression. The ligand moiety will recognize its binding partner (cellular receptor) whether the receptor is expressed at high levels, low levels or normal levels.

Therefore, the claims are not enabled by the specification such that one of skill in the art would be able to make or use a poxviral particle having targeted infection specificity towards target cells.

Applicant's arguments, see Remarks page 8, filed April 24, 2006, with respect to the enablement rejection of claim 5 under 35 U.S.C. 112, first paragraph, have been fully considered but are not persuasive. Applicant argues that the amendment to claim 5, where the phrase "differentially or overexpressed, wherein the differentially or overexpressed cellular protein comprises" was canceled, obviates the basis for the rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB

Agnieszka Boesen, Ph.D.

Examiner

May 18, 2006

Stacy B. Chen 5/18/06

Stacy B. Chen

Primary Examiner